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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,202	05/19/2006	Nathan Bryan Mantlo	X16094	2055
25885	7590	10/31/2007		
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 10/31/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

**Office Action Summary**

Application No.

10/580,202

Applicant(s)

MANTLO ET AL.

Examiner

Shawquia Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,9-14,16,28,29,32-34,46,48,51,52,56,59,60,74,75,77,83 and 84 is/are pending in the application.
- 4a) Of the above claim(s) 59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,9-14,16,28,29,32-34,46,48,51,52,56,74,75,77,83 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/19/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Claims 3, 9-14, 16, 28-29, 32-34, 46, 48, 51-52, 56, 59-60, 74-75, 77 and 83-84 are currently pending in the instant application.

### **I. *Priority***

The instant application is a 371 of PCT/US04/39775, filed on December 21, 2004 which claims benefit of 60/532,320, filed on December 22, 2003 and claims benefit of 60/586,563, filed on July 9, 2004 and claims benefit of Foreign Applications EPO 0438019.6, filed on July 21, 2004 and EPO 04380158.8, filed on July 21, 2004.

### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 19, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been fully considered by the examiner.

### **III. *Restriction/Election***

#### **A. *Election: Applicant's Response***

Applicants' election with traverse of the genus embracing the compound of Example 9(a) in the reply filed on October 4, 2007 is acknowledged. The traversal is on the ground(s) that: (1) that the exemplary groups set forth in the Examiner's present restriction requirement are neither an appropriate restriction of the present invention nor in compliance with the requirement of MPEP 814.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C.

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121 and 372. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that the exemplary groups set forth in the Examiner's present restriction requirement are neither an appropriate restriction of the present invention nor in compliance with the requirement of MPEP 814, wherein the restriction requirement must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted invention so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement. However the Examiner wants to point out that MPEP 814 relates to applications filed on under 35 USC 111. The instant application is a 371 case and follows PCT guidelines.

The Examiner wants to clarify that the five groups set forth in the previous Office Action are not the only groups possible but are only examples of the various inventions that are encompassed in the instant claims. Applicants are given the option of electing a species of compound so that the Examiner can group the species.

Applicants request that the Examiner includes the composition and use of products commensurate in scope with compounds of the elected genus. The Examiner will examine the composition claims commensurate in scope with compounds of the elected genus. Once the compound claims are considered allowable then the process

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claims will be rejoined according to MPEP 821.04.

The Examiner will group Applicants elected species of example 9(a) in the following group drawn to a compound of Formula Ic of claims 3, 9-14, 16, 28, 29, 32, 33, 34, 46, 48, 51-52, 56, 74, 75, 77, 83 and 84 wherein:

R1 is hydrogen;

R26, R27, R28 and R31 are each independently are as defined in claim 3 excluding heteroaryl and heterocycloalkyl;

R12, R13, R14, R15, R16, R17, R18, R19, R20, R21, R22, R23, R24 and R25 are each independently selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>6</sub> alkyl and aryl;

V is C<sub>0</sub>-C<sub>8</sub> alkyl;

X is a single bond;

U is an aliphatic linker wherein one carbon atom of the aliphatic linker is substituted with from one to four substituents each independently selected from R30;

Y is selected from the group consisting of C, O and S;

E is C(R3)(R4)A and wherein

(i) A is as defined in claim 3 excluding tetrazole;

(ii) each R<sup>7</sup> is as defined in claim 3;

(iii) R3 is C<sub>1</sub>-C<sub>2</sub> alkyl; and

(iv) R4 is methyl optionally substituted with from one to three substituents each independently selected from R26;

R8 is as defined in claim 3;

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R9 is as defined in claim 3 excluding heteroaryl;

R10 and R11 are as defined in claim 3 excluding heteroaryl-C<sub>0-4</sub>alkyl;

R12', R12'', R13', R14', R15', R16', R17', R18', R19', R20', R21', R22', R23',

R24' and R25' are as defined in claim 3;

R30 is as defined in claim 3 excluding heteroaryl-C<sub>0-4</sub>alkyl;

R32 is as defined in claim 3 and the dotted line is optionally a bond to form a double bond at the indicated position.

Subject matter not encompassed by the above group are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### IV. Rejections

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 9-14, 16, 28, 29, 32, 33, 34, 46, 48, 51-52, 56, 74, 75, 77, 83 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the variable Y is selected from the group consisting of C, O and S. However, Applicants have not defined C. Carbon has to have 4 bonds so the Examiner interprets C as referring only to CH<sub>2</sub>.

Claims 46, 48, 75, 77, 83 and 84 are rejected under 35 U.S.C. 112, second

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paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the structural formulae in claims 46, 48, 83 and 84 have two substituents R1 and R32 attached at variable possible points on the triazole ring. For example, in claim 46 the triazole ring has two double bonds bonded to two of the nitrogen atoms in the ring and also can have two substituents R1 and R32. The Examiner is not clear about where both of the substituents are bonded on the triazole ring. The substituents R1 and R32 can not be bonded to either of the two carbon atoms because both of the carbon atoms have 4 bonds already. Two of the nitrogen atoms are bonded to a carbon in the ring via a double bond and the other bond is to either another carbon atom or a nitrogen atom. The nitrogen atoms are satisfied with having 3 bonds and a 4 bond could be attached to the nitrogen atom but it would create a positive charge. Applicants have not indicated in the definitions or any of the examples present in the original specification that any of the nitrogen atoms in the triazole ring can possible have 4 bonds attached to the atom thus creating a positive charge. Therefore there can only be one substituent attached to the triazole ring of the structural formula VI, IX, the formula represented in claim 83 and the formula Ia. In claim 84, one of the nitrogen atoms in the triazole ring has a hydrogen atom bonded to it, therefore it cannot have double bonds bonded to this nitrogen atom.

Claims 3, 9-14, 16, 28, 29, 32, 33, 34, 46, 48, 51-52, 56, 74, 75, 77, 83 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the variable R32 is a substituent attached to the triazole ring.

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Applicants have in the definition of variable R32 that R32 could be a bond attached to the triazole ring. However, this is impossible because a bond cannot be a substituent attached to a cyclic compound by itself.

## V. Objections

### Claim Objection-Non Elected Subject Matter

Claims 3, 9-14, 16, 28, 29, 32, 33, 34, 46, 48, 51-52, 56, 74, 75, 77, 83 and 84 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

### Claim Objections

Claims 74 and 75 are objected to because of the following informalities: there are extra commas in the claim. Appropriate correction is required.

Claims 51, 75 and 77 are objected to because of the following informalities: in claims 51 and 75 a nitrogen atom in the triazole ring is missing a third bond and in claims 75 and 77 the triazole rings are not complete therefore are missing a bond. Appropriate correction is required.

### **Specification**

The disclosure is objected to because of the following informalities: various triazole rings in structural formulae represented on pages 80-97 and 120 are missing a bond to complete the triazole ring.

Appropriate correction is required.



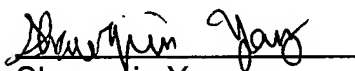
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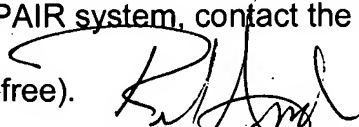
## VI. Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>re</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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